510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	March 21, 2012
Submitter:	GE Medical Systems, SCS (d.b.a. GE Healthcare) 283, rue de la Miniere BP34 78530 Buc Cedex - France FDA Registration Number: 9611343
Primary Contact Person:	Stephen Slavens, RAC Regulatory Affairs Director, MICT GE Healthcare Phone: (262) 548-4992 FAX: 262-548-3844 Stephen.Slavens@ge.com
Secondary Contact Person:	Helen Peng, RAC Regulatory Affairs Leader GE Healthcare Phone: (262) 548-5091 FAX: 262-548-3844 Hong.Peng@ge.com
Device: Trade Name:	CardIQ Xpress 2.0 with SnapShot* Freeze Option
Common/Usual Name:	Accessory to: System, x-ray, tomography, computed
Classification Names:	21CFR 892.1750
Product Code:	JAK
Predicate Device(s):	Predicate Device Name: CardIQ Xpress Version 2.0 Predicate 510k Number: K073138 Predicate Manufacturer: GE Medical Systems
Device Description:	The GE Medical Systems CardIQ Xpress 2.0 software is a post processing software option for the Advantage Workstation (AW) Platform, CT scanner, PACS or Centricity systems. This product can be used in the analysis of CT angiographic images to view the coronary vessels to determine if the patient has normal coronary arteries, arteriolosclerosis or severe stenosis, which needs to go on

for treatment. This software also can look at the heart structures to include valve imaging, heart motion and ejection fraction. CardIQ Xpress 2.0 contains both graphic and text report capabilities with predefined templates for ease of use.
CardIQ Xpress 2.0 with SnapShot* Freeze is additionally designed to reduce the coronary artery motion blurring in a CT image.

Indications for Use: CardIQ Xpress 2.0 is intended to provide an optimized non-invasive application to analyze cardiovascular anatomy and pathology and aid in determining treatment paths from a set of Computed Tomography (CT) Angiographic images. CardIQ Xpress 2.0 is a CT, noninvasive, image analysis software package, which aids in diagnosing of cardiovascular disease to include, coronary artery disease, functional parameters of the heart, heart structures and follow-up for stent placement, bypasses and plaque imaging.

CardIQ Xpress 2.0 offers unique tools such as automatic tracking, which will pre-process the CT data into multiple viewing ports to allow for an expedited read time improving workflow. With CardIQ Xpress 2.0, the user can color code the myocardial tissue to show hypo/hyper-dense areas in the myocardial tissue of the heart. With the IVUS-like view the user can color code the HU units of the plaque to better visualize the difference between calcified and non-calcified plaque in the wall of the vessel and the lumen to determine the amount of atherosclerosis. The user can see the different valve planes along with a variety of new layouts to align the heart. The IVUS like view is created by applying GE's Volume Rendering on a cross-section perpendicular to the detected centerline. This view merely displays a cross section as in IVUS imaging and color codes like IVUS images. No new or additional diagnostic information is added.

CardIQ Xpress 2.0 is for use on the Advantage Workstation (AW) platform, CT scanner, PAC or Centricity stations, which can be used in the analysis of 2D or 3D CT angiography

images/data derived from DICOM 3.0 CT scans.

Technology: The proposed medical device, CardIQ Xpress 2.0 with Snapshot Freeze Option, employs the same fundamental scientific technology as its predicate device CardIQ Xpress 2.0.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

CardIQ Xpress 2.0 with SnapShot Freeze Option complies with voluntary standards as discussed in Section 9, and 11 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

Summary of Clinical Tests:

As referenced in Section 20, the CT acquired clinical images used for the completion of verification and validation testing for CardIQ Xpress 2.0 with Snapshot Freeze Option were obtained from a non-significant risk reader study of care patient images.

Conclusion: GE Healthcare considers the CardIQ Xpress 2.0 with Snapshot Freeze Option application to be as safe, as effective, and performance is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 18 2012

GE Healthcare
c/o Mr. Stephen Slavens
Regulatory Affairs Director, MICT
3000 N Grandview Blvd W 1140
Waukesha, WI 53188

Re: K120910
Trade Name: CardIQ Xpress 2.0 with Snapshot Freeze Option
Regulation Number: 21.CFR892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II (two)
Product Codes: JAK
Dated: June 17, 2012
Received: June 22, 2012

Dear Mr. Slavens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

GE Healthcare

510(k) Premarket Notification Submission

510(k) Number (if known):

Device Name: CardIQ Xpress 2.0 with SnapShot* Freeze Option

Indications for Use:

CardIQ Xpress 2.0 is intended to provide an optimized non-invasive application to analyze cardiovascular anatomy and pathology and aid in determining treatment paths from a set of Computed Tomography (CT) Angiographic images. CardIQ Xpress 2.0 is a CT, noninvasive, image analysis software package, which aids in diagnosing of cardiovascular disease to include, coronary artery disease, functional parameters of the heart, heart structures and follow-up for stent placement, bypasses and plaque imaging.

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*ShapShot is a trademark of General Electric Company

Prescription Use_x___ AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use_ _ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) _____

Page 1 of _1_

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K120910